REMARKS

In the Office Action issued on June 6, 2006, the Examiner:

- made the previously issued Election/Restriction requirement final;
- withdrew Claims 5 through 7, 15 through 17, and 19 through 21 from further consideration as being elected to nonelected Species 2 through 7;
- requested resubmission of the non-patent literature cited in the Information Disclosure Statement filed on March 24, 2005;
- objected to the Abstract;
- objected to the specification for lacking a description of Figure 7;
- objected to Claims 2 through 4, 8 through 12, 14, and 18 for informalities;
- rejected claims 1 through 4 under 35 U.S.C. §102(b); and
- rejected claims 8 through 14 and 18 under 35 U.S.C. §103(a).

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's objections and rejections. Reconsideration of the application for patent is requested.

Election/Restriction requirement

The Examiner made the previously issued Election/Restriction requirement final and withdrew Claims 5 through 7, 15 through 17, and 19 through 21 from further consideration as being drawn to nonelected Species 2 through 7.

The Applicants note that the Examiner has previously acknowledged that Claim 1 is generic, and expressly reserve the right to pursue the withdrawn claims upon its allowance, through rejoinder practice or other appropriate procedure.

Information Disclosure Statement

The Examiner indicated that the Information Disclosure Statements filed by the Applicants are in compliance with 37 C.F.R. §1.97. However, the Examiner indicated that the Applicants should resubmit the non-patent literature disclosed in the March 24, 2005 Information Disclosure Statement.

At this time, the reason for the need for resubmission of these documents is not clear. Furthermore, the Applicants are not aware whether a newly filed

Information Disclosure Statement that includes the same documents would require a fee. Accordingly, the Applicants respectfully request a more thorough explanation for the need for resubmission and an indication of whether or not the applicable fee needs to be paid with the resubmission.

Objection to the Abstract

The Examiner objected to the Abstract, indicating that it "....should provide more detail in terms of the structures used for spacing the portion of the delivery device from the vessel wall and the steps of the method for spacing and deployment of the expandable intraluminal medical device."

The Applicants have herein amended the Abstract to include information pertaining to this objection.

The amendments made to the Abstract reflect information already present in the application; no new matter has been introduced. Exemplary support is found in Claim 1, paragraph 0037, and paragraph 0038.

The Applicants respectfully assert that the Abstract fully complies with the applicable requirements and request withdrawal of this objection.

Objection to the specification

The Examiner objected to the specification as not having a detailed description of Figure 7. The Applicants respectfully assert that Figure 7 is adequately described in the application as filed because Figure 7 is a sectional view of Figure 5, taken along line 7-7 (as noted in the Brief Description of the Drawings).

Nevertheless, the Applicants have herein amended the specification to include new paragraph 0039.1 that includes a description of Figure 7.

The amendments made to specification reflect information already present in the application; no new matter has been introduced. Exemplary support for the amendments is found in Figures 5 and 7, and paragraphs 0039 through 0044.

The Applicants respectfully assert that the specification fully complies with the applicable requirements and request withdrawal of this objection.

Objections to the Claims

The Examiner objected to Claims 2 through 4, 8 through 12, 14, and 18 for informalities. Specifically, the Examiner objected to Claims 2 through 4 and Claims 8 through 12 for referring to "**A** method for..." instead of "**The** method for...." Similarly, the Examiner objected to Claims 14 and 18 for referring to "**A** delivery system for..." instead of "**The** delivery system for...."

The Applicants have herein amended Claims 2 through 4 and Claims 8 through 12 to refer to "**The** method for...." Similarly, the Applicants have herein amended Claims 14 and 18 to refer to "**The** delivery system for...."

These amendments are made solely to address the informalities noted by the Examiner. The amendments are not considered narrowing in any manner. Furthermore, no new matter has been introduced.

Rejections of the claims under 35 U.S.C. §102

The Examiner rejected Claims 1 through 4 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 6,071,263 to Kirkman ("Kirkman"). Specifically, the Examiner indicated that Kirkman "discloses a method for delivering and deploying an expandable intraluminal device" that includes the steps recited in Claims 1 through 4 of the present application for patent.

To qualify as an anticipatory reference under 35 U.S.C. §102, a cited reference must disclose each and every limitation of the claim(s) under review. The Applicants respectfully assert that Kirkman fails to anticipate Claims 1 through 4 at least because it does not disclose the steps of "spacing a portion of the elongate member from a wall surface of the body vessel" and "deploying said expandable intraluminal medical device from the elongate member" as separate steps, which is required by each of Claims 1 through 4.

Claim 1, from which Claims 2 through 4 depend, specifically requires separate spacing and deploying steps. A complete review of Kirkman reveals a complete lack of any disclosure of a method that includes these separate steps. Indeed, review of the only figure in Kirkman that relates to deployment of an intraluminal medical device (Figure 10A) and the accompanying discussion (c.12, line 60 through c.13, line 51) reveals that the device and method disclosed in Kirkman is incapable of performing these steps separately. The anchoring wires 156, 158, 160 are the elements that function to space the catheter tip 8 from the vessel wall. As clearly illustrated in Figure 10A, the anchor wires are connected to the interior of the stent 154. Kirkman explains: "The stent 154 is connected to the catheter tip 8 by one or more connecting wires 156, 158, 160."

Because of this structural relationship between the intraluminal medical device (the stent 154) and the means for spacing (the connecting wires 156, 158, and 160), the method and device disclosed by Kirkman **must** accomplish spacing and deploying steps **simultaneously**. As a result, Kirkman cannot anticipate Claims 1 through 4, each of which require that these steps be accomplished separately.

Applicants respectfully assert that the rejection of Claims 1 through 4 is improper and request its withdrawal.

Rejections of Claims 8 through 11 under 35 U.S.C. §103

The Examiner rejected Claims 8 through 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Patent No. 5,534,007 to St. Germain *et al.* ("St. Germain"). Specifically, the Examiner indicated that Kirkman "discloses the claimed steps except for the delivery system further comprising a sheath that is circumferentially disposed about the elongate member, and wherein the step of deploying the expandable intraluminal device comprises retracting the sheath from a position about the expandable intraluminal medical device."

The Applicants respectfully asserts that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claims 8 through 11.

A *prima facie* case of obviousness requires three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. Second, there must be a reasonable expectation of success. Lastly, the references must teach or suggest all limitations of the claims. (See M.P.E.P. §2143).

The Examiner has failed to establish a *prima facie* case of obviousness at least because the cited references do not teach or suggest all limitations of the claims. As discussed above, Kirkman does not teach or suggest separate spacing and deploying steps, which is required by each of Claims 8 through 11 by way of their dependency on Claim 1.

A thorough review of St. Germain reveals that it does not cure this defect of Kirkman. As a result, the asserted combination of references fails to teach or suggest all limitations of Claims 8 through 11. Accordingly, a prima facie case of obviousness has not been established, and the Applicants are under no obligation to present evidence of nonobviousness.

Applicants respectfully request reconsideration of the rejection of Claims 8 through 11.

Rejections of Claim 12 under 35 U.S.C. §103

The Examiner rejected Claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Patent Application Publication No. 20010039450 to Pavcnik *et al.* ("Pavcnik"). Specifically, the Examiner indicated that "Kirkman discloses the claimed steps except for the expandable intraluminal medical device comprising a prosthetic venous valve" and asserts Pavcnik as curing this defect of Kirkman.

The Applicants respectfully asserts that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claim 12.

The Examiner has failed to establish a *prima facie* case of obviousness at least because the cited references do not teach or suggest all limitations of the claim. As discussed above, Kirkman does not teach or suggest separate spacing and deploying steps, which is required by Claim 12 by way of its dependency on Claim 1.

A thorough review of Pavcnik reveals that it does not cure this defect of Kirkman. As a result, the asserted combination of references fails to teach or suggest all limitations of Claim 12. Accordingly, a *prima facie* case of obviousness has not been established, and the Applicants are under no obligation to present evidence of nonobviousness.

Applicants respectfully request reconsideration of the rejection of Claim 12.

Rejections of Claims 13, 14, and 18 under 35 U.S.C. §103

The Examiner rejected Claims 13, 14, and 18 under 35 U.S.C. §103(a) as being unpatentably obvious over United States Patent Application Publication No. 20040087965 to Levine ("Levine") in view of Kirkman and Pavcnik. Specifically, the Examiner indicated that "Levine et al. discloses the claimed device except for the expandable intraluminal medical device 108 being circumferentially disposed about a portion of the elongate member 118." The Examiner looks to Kirkman to cure this defect of Levine, noting that "Kirkman teaches an expandable intraluminal medical device 154 which is circumferentially disposed about the distal portion of elongate member 4 (Figure 10A)."

The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claims 13, 14, and 18 at least because there is no suggestion or motivation to modify or combine the references as the Examiner proposes. Indeed, no such suggestion or motivation can be found because the proposed modification would render the device taught by Levine unsatisfactory for its intended purpose. (*See* M.P.E.P. §2143.01(V), *citing* In re Gordan, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)).

Levine indicates that the purpose of the disclosed device is to provide "a method and apparatus for caged stent delivery that affords greater control and greater access to intraluminal cavities having small circumferences." (paragraph 0009). In all disclosed devices, a series of arms that define a cage for containing a stent in a constricted form is attached to a distal end of a tubular portion. Levine explains that "[i]n operation, the cage carries a stent, in its smaller diametric form, to the site of deployment within a lumen of the body." (paragraph 0010).

Claim 13, from which Claims 14 and Claim 18 depend, requires that the elongate member have the expandable intraluminal medical device disposed about a portion of it and have an ancillary delivery device disposed in a lumen

defined by it. To modify the device taught by Levine in the manner suggested by the Examiner (*i.e.*, dispose the stent circumferentially about the elongate member 118), the stent 108 would have to be removed from the cage and disposed on the optional catheter 118, which the Examiner characterizes as the elongate member. This modification would render the device taught by Levine unsatisfactory for its intended purpose of providing a method and device for caged stent delivery.

Because of this purpose-defeating proposed modification to Levine, no motivation or suggestion to modify or combine the asserted references can be found. As a result, a *prima facie* case of obviousness based on the asserted combination of references cannot be established.

The rejections of Claims 14 and 18 also depend on this combination of references and, as such, fail for the same reason.

The Applicants respectfully request withdrawal of the rejection of Claims 13, 14, and 18.

CONCLUSION

The Applicants have fully responded to the objections and rejections listed by the Examiner in the June 6, 2006 Office Action. Applicants respectfully assert that all pending claims define patentable subject matter and request reconsideration and issuance of an appropriate Notice of Allowability.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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